***** FOR PUBLICATION *****

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE JOHNSON & JOHNSON DERIVATIVE LITIGATION,	:	Civil Action No. 10-2033 (FLW)
		OPINION

WOLFSON, United States District Judge:

This consolidated shareholder derivative action arises out of allegations that essentially accuse certain former and current officers and directors of nominal defendant company Johnson & Johnson ("J&J") of breaching their fiduciary duties by permitting and fostering a culture of systematic, calculated and widespread legal violations. In that sense, in the Consolidated Amended Complaint (the "Complaint"), the plaintiff-shareholders ("Plaintiffs") intimate that these board members deliberately and knowingly took no actions in curbing various illegal activities which occurred throughout J&J's business segments.

In the instant matter, J&J moves to dismiss the Complaint. Having failed to first make a demand to the Board of Directors (the "Board") of J&J, the Court must assess the sufficiency of plaintiff Shareholders' allegations through the lens of Rule 23.1, which requires a heightened pleading standard. In that regard, while under the

constraints of Rule 23.1, the Court finds that demand would not have been futile, the troubling and pervasive allegations against the Board may pose a greater difficulty for J&J if the Complaint were analyzed under a more liberal pleading standard. As this current motion stands, the Court will grant the relief J&J seeks and dismiss the Complaint for the reasons that follow.

I. BACKGROUND

A. Facts

On a motion to dismiss, I take, as I must, Plaintiffs' allegations as true. Plaintiffs' complaint generally consists of allegations of a series of "red flags" that Plaintiffs allege placed the Board on notice of serious corporate conduct that occurred in various divisions, or subsidiary corporations, of J&J. In this background section, I provide an overview of the extensive allegations found in Plaintiffs' ninety-seven page complaint. I provide further detail about Plaintiffs' allegations, where appropriate, in connection with my analysis later in this Opinion.

J&J, a global health care company incorporated in New Jersey, is a holding company that consists of over 250 subsidiaries.[1] While some of these subsidiaries are

[1] The facts I recite in this paragraph, regarding J&J's corporate structure, are derived from J&J's 2011 Security Exchange Commission Form 10-K filing. See Form 10-K, Annual Report for the fiscal year ending January 2, 2011 (Feb. 25, 2011) (Part I) available at www.investor.nj.com/governance/sec-filings.cfm. Under Federal Rule of Evidence 201, the court may take judicial notice of facts gathered from "sources whose accuracy cannot reasonable be questioned." Fed.R.Evid. 201(b)(2). The Third Circuit has held this rule to permit judicial notice of properly authenticated documents filed with the SEC. See Oran v. Stafford, 226 F.3d 275, 289 (3rd Cir. 2000). In taking judicial notice of these documents, the Court may rely upon them "to determine what the documents stated." Id. (quoting Kramer v. Time Warner, Inc., 937 F.2d 767, 774

domestic, others operate abroad. J&J categorizes its subsidiaries into three segments: consumer, pharmaceutical, and medical devices. See Compl., ¶ 47. For each of its subsidiaries, J&J employs principles of decentralized management. So, foreign subsidiaries are generally managed by citizens of the country where the subsidiary is located. As described in more detail below, Plaintiffs' allegations relate to seven of J&J's 250 subsidiaries.

The members of the Board, at the time of Plaintiffs' initial complaint, were Defendants Mary Sue Coleman, Ph.D., James Cullen, Susan Lindquist, Ph.D., Leo Mullin, David Satcher, M.D., Ph.D., William Weldon, Anne Mulcahy, Michael Johns, M.D., William Perez, Arnold Langbo, and Charles Prince. Of these directors, most of them served during the entire time frame addressed in the Complaint, 2003 through 2010. All the directors are outside directors, with the exception of William Weldon, J&J's Chairman and Chief Executive Officer ("CEO"). The Complaint does not make any allegations of wrongdoing against Mulcahy, thus, the Court's demand-futility analysis will focus on the other ten directors.

Altogether, Plaintiffs' allegations describe several types of red flags from which the Court should infer that the ten directors attained knowledge of J&J's untoward corporate acts. These red flags take the form of FDA warning letters, an FDA report, state attorney general subpoenas, qui tam complaints, a criminal plea, a settlement agreement with the U.S. Department of Justice ("DOJ"), and a DOJ subpoena. The red

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(2d Cir.1991)).

flags cover three substantive categories of alleged corporate misconduct: (a) product recalls; (b) off-label marketing of drugs; and (c) illegal kick-backs. I describe Plaintiffs' specific red flag allegations in the context of these categories.

A. Product Recall Allegations

Plaintiffs generally allege that three J&J subsidiaries violated federal drug regulations and that, as a result, J&J was required to recall four sets of products.[2] The first three recalls relate to J&J subsidiary McNeil Consumer Healthcare ("McNeil"). Plaintiffs first allege that McNeil engaged in a "phantom recall" of certain packages of Motrin. See Compl., ¶¶ 95-102. The second recall was also by McNeil, and refers specifically to over-the-counter ("OTC") products manufactured at its Las Piedras Plant where the delayed discovery of chemically-treated wood pallets caused "uncharacteristic odors" to seep into the OTC products. See id. at ¶¶ 103-12. The complaint alleges that the FDA mailed J&J a warning letter addressed to Weldon in 2008, and inspected the facility in 2010.

The third recall relates to McNeil's Fort Washington Plant where children's and infants' versions of Tylenol, Motrin, Zyrtec, and Benadryl were manufactured. Id. at ¶¶ 113-25. That facility was inspected by the FDA in April 2010 and, subsequently, between October and December of that year. On April 30, 2010, the Complaint alleges,

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[2] I clarified with J&J counsel at oral argument that the J&J subsidiaries are wholly owned by J&J. Accordingly, the parties agreed that there was no need for Plaintiffs to make demand upon, or demonstrate demand-futility with respect to, the boards of the subsidiary corporations. Where relevant, the J&J subsidiary will be identified by name. Where the subsidiary's name is not relevant, I will refer to "J&J" as encompassing its wholly owned subsidiaries.

J&J initiated a recall of infant and children's liquid medicines on account of manufacturing deficiencies at the Fort Washington Plant. Id. at ¶ 122.

Finally, Plaintiffs allege that two other subsidiaries recalled medial products. According to Plaintiffs, J&J's Vision Care, Inc. subsidiary instituted a voluntary recall on August 18, 2010, following complaints of irritation and pain by users of Acuvue contact lenses. Id. at ¶¶ 126-27. Similarly, Plaintiffs allege that J&J subsidiary DePuy Orthopaedics ("DePuy") recalled certain hip replacement devices on August 24, 2010. Id. at ¶ 135. This recall was necessary in light of the FDA's ordering of J&J to cease selling the Corail Hip System because J&J had been marketing the hip system for unapproved use. Id.

For the various recalls, Plaintiffs allege that several newspaper articles, statements by confidential witnesses, qui tam suits, civil suits, congressional testimony and FDA documents constitute "red flags" that placed the Board on notice of systemic violations within J&J. Furthermore, Plaintiffs allege that McNeil is under federal criminal investigation. Id. at ¶ 158. However, the Complaint does not specify the nature or subject matter of this investigation.

B. Off-Label Marketing

Plaintiffs allege that several J&J subsidiaries engaged in an extensive off-label marketing campaign for three drugs—Risperdal, Topomax, and Natrecor—over several years. While doctors may prescribe FDA approved drugs for uses for which the drug is not approved, it is illegal for drug companies to market drugs for such "off-label" use. Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 350-51 (2001). In support of its

off-label allegations, the Complaint details a hodge-podge of internal J&J reports, news articles, and FDA warning letters issued to J&J, from 1999 onward, for both the Risperdal and Topomax medications. See Compl., ¶¶ 171-208. Plaintiffs' Natrecor allegations, in contrast, relate both to J&J's acquisition of the company that initially developed the drug, as well as the post-acquisition off-label marketing of the drug.

With respect to Risperdal, an antipsychotic drug, Plaintiffs allege that the J&J subsidiary Janssen Pharmaceutica, Inc. ("Janssen"), marketed the drug for off-label uses. See id. at ¶¶ 168-92. For Topomax, Plaintiffs allege that J&J subsidiary Ortho-McNeil Pharmaceutical, Inc. ("Ortho") aggressively marketed off-label uses after the drug was respectively approved in 1996, 1999, and 2004 for three distinct, but specific, uses.[3] Id. at ¶ 193. With respect to Natrecor, Plaintiffs allege that drug was initially developed by Scios, Inc. ("Scios"), a company subsequently acquired by J&J in 2003 with board approval, "following comprehensive due diligence." Id. at ¶ 209, 213. According to Plaintiffs, Scios marketed Natrecor for off-label uses although it was approved only for treating patients with congestive heart failure. See id. at ¶¶ 209-40.

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[3] Plaintiffs' Complaint refers to the subsidiary that marketed Topomax as "J&J's McNeil subsidiary." Id. at ¶ 207. J&J, in its moving brief, clarifies that Topomax was marketed by Ortho-McNeil Pharmaceutical, Inc. ("Ortho"). See Def. Open. Br. at 9. This entity, while bearing a similar name to the McNeil Consumer Healthcare subsidiary that manufactures over the counter drugs, see Compl., ¶ 109, is a distinct entity. That it is a distinct entity is confirmed by J&J's 2008 10-K Statement, which lists McNeil Consumer Healthcare and Ortho as separate subsidiaries. Johnson & Johnson Form 10-K (Annual Report) for period ending December 30, 2007 at Exhibit 21 ("2008 10-K") (emphasis added). For reasons explained in more detail below, the Court takes judicial notice of this 10-K and, accordingly, construes Plaintiffs' allegations regarding Topomax as relating to the Ortho subsidiary as opposed to the McNeil subsidiary.

Finally, Plaintiffs allege that J&J subsidiary Cordis Corporation ("Cordis") was marketing biliary stents for off-label uses. Id. at ¶¶ 241-53. Biliary stents are medical devices implanted in the bile duct of cancer patients to aid drainage. Id. Plaintiffs allege that Cordis induced physicians to prescribe the stents for use in the vascular system. Id. at ¶ 242.

Plaintiffs allege that several red flags alerted the directors to each of these off-label marketing schemes. As with Plaintiffs' recall allegations, the alleged red flags range from qui tam complaints and medical journal articles, to FDA warning letters and government agency subpoenas.

C. Omnicare and DePuy Kick-Back Allegations

Plaintiffs' kickback allegations focus on the Board's conduct in failing to remedy J&J's subsidiaries' use of illegal kickbacks to bolster sales. Specifically, the Complaint first alleges that J&J subsidiaries' Janssen and Johnson & Johnson Health Care Systems, Inc. ("HCS") paid kickbacks to Omnicare, Inc. ("Omnicare"). Id. at ¶ 255. Omnicare is a company that provides pharmacy-related services to nursing home-based patients. Id. In assisting those patients, Omnicare submits reimbursement claims on the patients' behalf. It is alleged that J&J entered into a "Drug Supply Agreement" with Omnicare that provided rebates to Omnicare based on the amount of J&J drugs that Omnicare purchased. Id. at ¶ 258. On account of the agreement, Omnicare convinced the nursing home patients' physicians to switch the patients from non-J&J drugs to J&J drugs. Id. at ¶ 270.

Plaintiffs allege, among other things, that Omnicare entered into a settlement

agreement with the DOJ on November 2, 2009, to resolve allegations by the DOJ, that Omnicare solicited and received kickbacks from J&J. Id. Thereafter, in early 2010, the DOJ intervened in a *qui tam* suit against J&J related to J&J's role in encouraging Omnicare to promote its drugs. Id. at ¶ 271. Plaintiffs' Complaint does not address the result of the *qui tam* action, perhaps because the DOJ intervened only several months prior to the filing of the instant Complaint. Finally, Plaintiffs allege that the directors "understood" that the kickbacks violated the Federal Anti-Kickback Statute and were illegal. Id. at ¶ 257.

With respect to DuPuy, Plaintiffs allege that DuPuy paid kickbacks to surgeons from January 2002 through December 2006 to induce them to use DePuy hip and knee replacements and reconstructive products. Id. at ¶¶ 273-77. According to the Complaint, the company received a DOJ subpoena in 2005, and a criminal complaint was filed against DuPuy in September of 2007. That criminal complaint was ultimately settled, which settlement resulted in a payment by J&J of $84.7 million dollars, Deferred Prosecution Agreement, and a Corporate Integrity Agreement ("CIA"). Id. at ¶ 274. None of Plaintiffs' DePuy allegations point to any specific board members, or suggest how any of the directors knew that J&J was engaging in illicit conduct at that time. As with Plaintiffs' other allegations, the Complaint asserts these various red flags placed the Board on notice, and that the Board failed to properly respond.

D. Remaining Allegations

Plaintiffs, further, allege that several of the directors served on the Board's audit

committee, public policy advisory committee, and science and technology committee. Based upon the directors' participation in these committees, Plaintiffs allege that the directors "had substantial knowledge relating to the allegations above and with such knowledge, knowingly permitted the Company to continue to pursue its unlawful and unethical business practices and strategies." Id. at ¶ 301.

In addition, Plaintiffs allege that all the directors signed the company's 10-K forms, "which disclosed *many of the red flags* and which the Director Defendants on the Board at the time of each Form 10-K reviewed and executed." Id. at ¶ 279 (emphasis added). Plaintiffs' counsel clarified, at oral argument, that the 10-Ks disclosed subpoenas that had been filed against certain J&J employees. No further specific allegations are made with respect to the knowledge, actions, or inactions of each director. Based on these allegations, the Complaint asserts two counts: (1) Count I - breach of fiduciary duties against the directors; and (2) Count II - breach of fiduciary duties against the officers.

E. Procedural History

On April 21, 2010, co-lead plaintiff Jeanne M. Calamore filed her derivative complaint. Over the course of the next several months, other shareholders filed five additional derivative complaints. Each of these shareholders filed suit without having first made a demand on J&J's Board.

Thereafter, on August 17, 2010, the Court consolidated the six derivative cases into the instant action titled In re Johnson & Johnson Derivative Litigation, Case No. 10-cv-2033. On December 17, 2010, Plaintiffs filed the Consolidated Amended

Complaint that is the subject of this motion. Therein, Plaintiffs assert that they did not make a demand because demand would have been futile. Following the filing of the Consolidated Amended Complaint, nine other shareholders made demands upon J&J's Board with respect to matters alleged in the Complaint. J&J filed the instant motion to dismiss and to stay the litigation, pending the Board's appointment of a Special Committee to review and investigate the demand shareholders' assertions, on February 21, 2011. That same day, the individual defendants, officers and directors alike, named in Plaintiffs' Complaint joined J&J's motion to dismiss.

Meanwhile, in April 2010, the Board appointed the Special Committee to consider the demand shareholders' assertions and the allegations made in the Complaint. The Special Committee was comprised of four independent directors, Michael Johns, Anne Mulcahy, William Perez, and Charles Prince, which directors had most recently joined the Board at the time the Committee was formed. The Special Committee, further, retained independent counsel. The investigation took over one year to complete.

On July 18, 2011, while the instant motion to dismiss and to stay was pending, the Special Committee issued its recommendation that the Board take no action with respect to the instant litigation. The Board subsequently adopted the Special Committee's recommendation. Shortly after the Board adopted the report, the Court held oral argument on the instant motion on July 28, 2010.

Because the Board has responded to the demand shareholders' requests, that aspect of J&J's motion seeking a stay is now moot. J&J's motion to dismiss, however,

is now ripe for decision. In that motion, J&J argues that Plaintiffs fail to satisfy the heightened pleading standard applicable to shareholder derivative actions found in Federal Rule of Civil Procedure 23.1. To be clear, those plaintiffs in the related actions that presented their demand to the Board are not subject to dismissal under Rule 23.1. This motion is pertinent to the Plaintiffs in this matter simply because they chose to file their complaint without first giving the Board the opportunity to address a demand. Keeping in mind the heightened standard applicable to plaintiffs who, like here, chose to proceed without first filing a demand on the Board, the Court agrees that Plaintiffs have failed to satisfy Rule 23.1 and grants J&J's motion to dismiss without prejudice. Plaintiffs are, further, granted leave to amend their complaint in a manner consistent with the strictures of this Opinion.

II. STANDARD OF REVIEW

A. Motion to Dismiss Standard

In reviewing a motion to dismiss for failure to state a claim under 12(b)(6), a court must take all allegations in the complaint as true, viewed in the light most favorable to the plaintiff "and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." Phillips v. County of Allegheny, 515 F.3d 224, 233 (3d Cir. 2008) (citation and quotations omitted). In Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007), the Supreme Court "retired" the language in Conley v. Gibson, 355 U.S. 41, 45–46, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957), that "a complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his

claim which would entitle him to relief." Twombly, 550 U.S. at 561 (quoting Conley, 355 U.S. at 45–46). Rather, the factual allegations in a complaint "must be enough to raise a right to relief above the speculative level." Id. at 555. In short, "a complaint must do more than allege the plaintiff's entitlement to relief. A complaint has to 'show' such an entitlement with its facts." Fowler v. UPMC Shadyside, 578 F.3d 203, 211 (3d Cir. 2009).

B. Shareholder Derivative Litigation Standard

Under Federal Rule of Civil Procedure 23.1, "a shareholder may file a derivative suit against the board of directors to claim enforcement of a right of the corporation where the corporation has failed to assert that right." Kanter v. Barella, 489 F.3d 170, 176 n.5 (3d Cir. 2007). Rule 23.1 contains specific requirements for a plaintiff's pleadings in derivative suits; a plaintiff must "allege with particularity the efforts, if any, made by the plaintiff to obtain the action the plaintiff desires from the directors or comparable authority ..., and the reasons for the plaintiff's failure to obtain the action or for not making the effort." In re PSE&G Shareholder Litig., 173 N.J. 258 (2002) ("PSE&G") (quoting Fed.R.Civ.P. 23.1).[4] "The purpose of Rule 23.1's demand requirement is to 'affor[d] the directors an opportunity to exercise their reasonable business judgment and waive a legal right vested in the corporation in the belief that its best interests will be promoted by not insisting on such right." Id. at 176. As a

[4] In addition, "the plaintiff must allege ownership of shares, or subsequent ownership by operation of law, at the time of the challenged transaction, [and further allege that] the federal courts have jurisdiction to hear the action." Id.

federal court hearing a shareholders' derivative suit involving state law claims, a district court must "apply the federal procedural requirement of particularized pleading, but apply state substantive law to determine whether the facts demonstrate demand would have been futile and can be excused." Id.

As with any Rule 12(b)(6) motion, in ruling on a motion to dismiss for failure to satisfy the shareholder derivative suit particularity standard, the court is "required to accept as true all allegations in the complaint and all reasonable inferences that can be drawn therefrom, and view them in the light most favorable to the plaintiff." Kanter, 489 F.3d at 177, 178 n.9. However, the Court need not credit bald assertions or legal conclusions found within a complaint. Id. at 177-78.

III. DISCUSSION

As noted, Defendant J&J has moved to dismiss the consolidated demand futility complaints for failure to satisfy the pleading standard set forth in Federal Rule of Civil Procedure 23.1, and the New Jersey Supreme Court decision in PSE&G. The demand-futility plaintiffs argue, in response, that they have sufficiently plead with particularity. Both parties agree that the Court should limit its review to the pleading allegations, and should not consider the J&J Board's acceptance of the report by the Special Committee. They further agree that the Court should not order discovery at this juncture. Hence my analysis focuses on the Complaint's allegations and adjudges those allegations in accordance with New Jersey law.[5]

[5] As noted, Plaintiffs' initial complaint was filed on April 21, 2010. An amended complaint was filed on December 17, 2010, and J&J's motion to dismiss was

A. New Jersey Demand-Futility Law

Federal Rule of Civil Procedure 23.1 provides the mechanism for judging the sufficiency of shareholders' derivative pleadings against a corporation "to enforce a right of a corporation [where the corporation] failed to enforce a right which may properly be asserted by it ...." Fed.R.Civ.P. 23.1. As explained by the court in In re Veeco Instruments, Inc. Securities Litigation, 434 F.Supp.2d 267 (S.D.N.Y. 2006):

> Since claims asserted in a shareholder derivative suit belong to the corporation, it is incumbent upon shareholder plaintiffs to make a demand upon the corporation's board of directors prior to commencing an action. Indeed, "A shareholder's right to bring a derivative action does not arise until he has made a demand on the board of directors to institute such an action directly, such demand has been wrongfully refused, or until the shareholder has demonstrated, with particularity, the reasons why pre-suit demand would be futile." This requirement stems from the well-settled principle that directors, rather than shareholders, manage the affairs of the corporation, and that the decision to bring or not to bring a lawsuit is a decision concerning the management of the corporation.

Id. at 273 (internal citations omitted).

In PSE&G, the New Jersey Supreme Court explained that, under its own procedural rule, New Jersey Rule of Court 4:32-3, and by drawing on case law from Delaware, that demand-futility plaintiffs

> must plead with particularity facts creating a reasonable doubt that: (1) the directors are disinterested and independent, or (2) the challenged transaction was

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filed in February, 2011. The parties agree that the Court should focus its analysis on the amended complaint, but that the Court should consider only those allegations that took place prior to April 21, 2010, the date of the original complaint. Tr. 7:22-9:5.

> otherwise the product of a valid exercise of business judgment. If either prong is satisfied, demand will be excused under [Rule 4:32-3].

PSE&G, 173 N.J. at 310. This test is referred to as the "Aronson test," named after the Delaware case upon which the PSE&G Court based its ruling, Aronson v. Lewis, 473 A.2d 805, 815 (Del. 1984), overruled on other grounds by Brehm v. Eisner, 746 A.2d 244 (Del. 2000). When applying the Aronson test, if the first prong is not satisfied, i.e., that the directors are disinterested and independent, then "there is a presumption that the Board's actions were the product of a valid exercise of business judgment." In re Intel Corp. Derivative Litig., 621 F.Supp.2d 165, 170 (D.Del. 2009) ("In re Intel") (citing Beam v. Stewart, 845 A.2d 1040, 1049 (Del. 2004)).

When the complaint is based on the board's inaction, it is "impossible to perform the essential inquiry contemplated by [the second prong in] Aronson, whether the directors have acted in conformity with the business judgment rule in approving the challenged transaction." Kanter v. Barella, 489 F.3d 170, 177 (3d Cir. 2007) (quoting PSE&G, 173 N.J. at 309). Accordingly, where board inaction has been alleged, New Jersey courts apply the "Rales" test to determine if demand would have been futile. See Johnson v. Glassman, 401 N.J.Super. 222, 243-44 (App.Div. 2007) (applying Rales to claim of board's general "lack of action").

The Rales test, derived from Rales v. Blasband, 634 A.2d 927, 934 (Del.1993), and adopted by the PSE&G Court, asks

> whether or not the particularized factual allegations of a derivative stockholder complaint create a reasonable doubt that, as of the time the complaint is filed, the board of

> directors could have properly exercised its independent and disinterested business judgment in responding to a demand.

Kanter, supra at 177 n.8 (quoting Rales, 634 A.2d at 934) (emphasis added). That the directors would face a "substantial likelihood' of personal liability by complying with a shareholder's demand to pursue litigation," is one means by which a plaintiff may adequately allege that a board could not have properly exercised independent and disinterested business judgment. In re Intel, 621 F.Supp.2d at 170-71. However, a court may not infer that a director that faces only the "mere threat of personal liability" is not disinterested. Rales, 634 A.2d at 936 (citing Aronson, 473 A.2d at 815).

As explained in In re SFBC Intern., Inc. Securities & Derivative Litig., 495 F.Supp.2d 477 (D.N.J. 2007) ("SFBC"), when "[p]laintiffs premise their theory of personal liability against the directors on their alleged failure to take any action to remedy the numerous problems plaguing [the company]," the theory of liability discussed by the Delaware Court of Chancery in In re Caremark Int'l, 698 A.2d 959 (Del.Ch.1996), applies. Id. at 484. With respect to director liability, Caremark explains:

> Director liability for a breach of the duty to exercise appropriate attention may, in theory, arise in two distinct contexts. First, such liability may be said to follow from a board decision that results in a loss because that decision was ill advised or "negligent". Second, liability to the corporation for a loss may be said to arise from an unconsidered failure of the board to act in circumstances in which due attention would, arguably, have prevented the loss.

698 A.2d at 967 (emphasis added).

Furthermore, the Caremark court notes that directors are often uninformed about business decisions, made by management and employees of the corporation, that "vitally affect the welfare of the corporation and its ability to achieve its various strategic and financial goals." 698 A.2d at 968. Caremark explains that

> Most of the decisions that a corporation, acting through its human agents, makes are, of course, not the subject of director attention. Legally, the board itself will be required only to authorize the most significant corporate acts or transactions: mergers, changes in capital structure, fundamental changes in business, appointment and compensation of the CEO, etc.

Id.

Although directors may not be aware of the business decisions made by the corporation through its various human agents, Caremark nonetheless holds that directors may be liable for failing to ensure that the corporation has

> information and reporting systems . . . that are reasonably designed to provide to senior management and to the board itself timely, accurate information sufficient to allow management and the board, each within its scope, to reach informed judgments concerning both the corporation's compliance with law and its business performance.

Id. at 970. In this way, directors may not merely place their "heads in the sand" to avoid liability and responsibility. Making clear that such behavior is unacceptable, the Caremark Court explicitly held that "a director's obligation includes a duty to attempt in good faith to assure that a corporate information and reporting system, which the board concludes is adequate, exists ...." Id. In that court's view, "failure to do so under some circumstances may, in theory at least, render a director liable for losses caused

by non-compliance with applicable legal standards." Id.

Very few Caremark claims are successful, however, and the Caremark theory has often been described as "possibly the most difficult theory in corporation law upon which a plaintiff might hope to win a judgment." In re Caremark, 698 A.2d at 967; see Veeco, 434 F.Supp.2d at 276. Cases in the Third Circuit applying Caremark have distilled that court's holding into a three-part test:

> (1) that the directors knew or (2) should have known that violations of law were occurring and, in either event, (3) that directors took no steps in a good faith effort to prevent or remedy that situation ...[6]

King v. Baldino, 409 Fed.Appx. 535, 537-38 (3d Cir. 2010) (emphasis added). See also SFBC, 495 F.Supp.2d at 485.

"Alternatively, a plaintiff may plead facts showing that 'the directors were conscious of the fact they were not doing their jobs,' and that they 'ignored 'red flags' indicating misconduct in defiance of their duties." King, 409 Fed.Appx. at 537 (citation omitted). "Red flags' in this context are 'facts showing that the board . . . was aware that [the corporation's] internal controls were inadequate." Id. (quoting Stone v. Ritter, 911 A.2d 362, 370 (Del. 2006)).

Allegations of bad faith on the part of the directors are central to a successful Caremark red-flag pleading. Indeed, recent Delaware state and federal decisions describe the Caremark theory as one rooted in allegations of bad faith. One court

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[6] There is a fourth-part — that such failure proximately resulted in the losses complained of — but that prong is an affirmative defense that need not be plead in the complaint. Id. at 538, 538 n.2.

explains that Caremark

> encouraged directors to act with reasonable diligence, but plainly held that director liability for failure to monitor required a finding that the directors acted with the state of mind traditionally used to define the mindset of a disloyal director—bad faith—because their indolence was so persistent that it could not be ascribed to anything other than a knowing decision not to even try to make sure the corporation's officers had developed and were implementing a prudent approach to ensuring law compliance.

In re Citigroup Inc. Shareholder Derivative Litig., 964 A.2d 106, 123 (Del.Ch. 2009) ("Citigroup") (emphasis added) (quoting Desimone v. Barrows, 924 A.2d 908, 935 (Del.Ch. 2007), and discussing Stone, 911 A.2d at 369).

The dictate that plaintiffs must plead bad faith allegations is heightened when the directors are entitled to the protections of an exculpatory charter that insulates directors from liability for acts or omissions in the course of their director duties. Such exculpatory charters are recognized and enforced by New Jersey courts, but such charters may not limit a director's liability for acts or omissions committed in bad faith.[7] "Where, as here, directors are exculpated from liability except for claims based

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[7] The Third Circuit, in Kanter, explains:

> New Jersey allows a corporation to include an exculpatory provision for its directors and officers in its charter. Such provisions, however, cannot exculpate directors and officers from "any breach of duty based upon an act or omission (a) in breach of such person's duty of loyalty to the corporation or its shareholders, (b) not in good faith or involving a violation of law or (c) resulting in receipt by such person of an improper personal benefit."

489 F.3d at 182 n.15 (quoting N.J.S.A. § 14A:2-7). See also PSE&G, 173 N.J. at 295.

on 'fraudulent,' 'illegal' or 'bad faith' conduct, a plaintiff must also plead particularized facts that demonstrate that the directors acted with scienter, i.e., that they had 'actual or constructive knowledge' that their conduct was legally improper." Wood v. Baum, 953 A.2d 136, 141 (Del. 2008). Referencing similar clauses that are enforceable under Delaware law, the court in Desimone explains, "[b]y reinforcing that a scienter-based standard applies to claims in the delicate monitoring context, [courts] ensure[ ] that the protections that exculpatory charter provisions afford to independent directors against damage claims [are] not be eroded." 924 A.2d at 935.

In this connection, Kanter explains that it is essential to a Caremark pleading that a plaintiff allege that the directors were "conscious of the fact that they were not doing their jobs." Kanter, 489 F.3d at 181; id. at 177 (describing actual knowledge requirement). Moreover, the complaint must provide particularized allegations from which the court can infer the board had knowledge of the allegedly corrupt corporate conduct and either "knew they were not discharging their fiduciary obligations or that they demonstrated a conscious disregard for their duties." Intel, 621 F.Supp.2d at 174 (quoting Citigroup, 964 A.2d at 122-23). Thus, "while directors could be liable for a failure to monitor, only a sustained or systematic failure of the board to exercise oversight—such as an utter failure to attempt to assure a reasonable information and reporting system exists—will establish the lack of good faith that is a necessary condition to liability." Citigroup, 964 A.2d at 122 (emphasis added).

Finally, there are three ways in which shareholder derivative plaintiffs may allege that a director is not disinterested and independent. Plaintiffs may allege that

a director received a personal benefit from his or her action or inaction, or that a director is under the control of another Board member and fails to exercise independent judgment. Johnson, 401 N.J.Super. at 239-40, 243. Alternatively, plaintiffs may allege that the director faces a substantial likelihood of personal liability for the challenged action or inaction and, therefore, could not fairly represent the corporation's interests. Id. at 243. In short, "[a] director is independent if he can base his decision 'on the corporate merits of the subject before the board rather than extraneous considerations or influence." Veeco, 434 F.Supp.2d at 275 (quoting Seminaris v. Landa, 662 A.2d 1350, 1354 (Del. Ch. 1995)). Whether a director is disinterested and independent is a fact-intensive inquiry. Id. at 239.

Plaintiffs' allegations, here, focus on whether the directors face a substantial likelihood of personal liability for their failure to act in the face of serious corporate misconduct. In ascertaining whether a director faces such liability, courts may infer, from particularized allegations of red flags, that directors knew of corporate misconduct. Courts will make such inferences where there are "well-pleaded facts from which it can be reasonably inferred that this [red flag] was knowable and that the defendant was in a position to know it." Citigroup, 964 A.2d at 135 n.93.

Moreover, even when allegations suggest that a director knew of a given red flag, that mere knowledge "do[es] not support a reasonable inference that the director defendants' [failure to act] . . . was not in good faith." Id. In other words, Plaintiffs must plead specific facts from which the Court can infer not simply a failure to act but a failure to act in bad faith. Plaintiffs may accomplish this by pleading, for example,

facts from which the Court may infer that the directors knew that their failure to act would have breached their fiduciary duties to the corporation, or that their conduct was otherwise "legally improper." Intel, 621 F.Supp.2d at 171. This is because directors are not exculpated from liability, under a corporation's exculpatory charter, for "claims based on fraudulent, illegal or bad faith conduct ...." Wood, 953 A.2d at 141.

B. Analysis

In light of the weighty allegations of corporate misconduct and director inaction in the instant Complaint, I find the following comments by the Delaware Supreme Court in Brehm v. Eisner, 746 A.2d 244 (Del. 2000), appropriate here:

> This is a case about whether there should be personal liability of the directors of a . . . corporation to the corporation for lack of due care in the [corporate] decisionmaking process and .... This case is not about the failure of the directors to establish and carry out ideal corporate governance practices.

Id. at 255.

The Brehm Court further explained that, while "[a]ll good corporate governance practices include compliance with statutory law and case law establishing fiduciary duties," the inverse is not true. Id. at 255. In other words, "the law of corporate fiduciary duties and remedies for violation of those duties are distinct from the aspirational goals of ideal corporate governance practices." Id. at 255-56. This means that "aspirational ideas of good corporate governance practices for boards of directors . . . are not required by the corporation law and do not define standards of liability." Id. at 255-56. I find these words appropriate in this case where Plaintiffs' allegations

suggest that the J&J Board did not live up to aspirational ideals, yet Plaintiffs have failed to allege that the directors acted in bad faith to violate their fiduciary duties.

Here, Plaintiffs allege that the numerous red flags recounted in the Complaint demonstrate that the Board members had knowledge of J&J's illegal and irresponsible practices that ultimately caused the company financial harm, yet the directors failed to act to stop the company's illicit behavior. As noted, "[t]hese red flags came in the form of federal and state regulatory investigations, subpoenas and requests for documents, FDA Warning Letters, news articles and the recall of products accounting for hundreds of millions of dollars of corporate losses." Compl., ¶ 278.

Because Plaintiffs' allegations do not speak to any particular action of the Board, but rather Board inaction, the Rales test applies here. Because Plaintiffs also allege that the Board's oversight committees failed to adequately oversee the company's activities, the Caremark theory of inadequate oversight is also applicable. Whether described as a Caremark theory or not, the touchstone of the demand-futility analysis is whether a majority of the Board members "could have properly exercised its independent and disinterested business judgment in responding to a demand." Rales, 634 A.2d at 934. I refer to this analysis, at times, as the "disinterested director test" or "disinterested director analysis."

1. Applicability of the Aronson Test

To be sure, Plaintiffs argue that their allegations may also fall under the Aronson test for director action by characterizing their allegations as establishing that the directors consciously decided not to act. Suffice it to say that some courts have

adopted this type of reasoning, which derives from the Seventh Circuit's decision in In re: Abbott Labs. Derivative S'holders Litig., 325 F.3d 795 (7th Cir. 2001). However, the Third Circuit has expressed reservations about applying Abbott's reasoning to New Jersey corporations. See Fagin, 432 F.3d at 282-83. Moreover, the New Jersey Supreme Court has yet to address Abbott, and New Jersey lower court decisions have applied it only to those limited circumstances in which a complaint alleges "extreme indifference." Fagin v. Gilmartin, 2007 WL 2176482 at *11 (Ch. Div. 2007); see Johnson, 401 N.J.Super. at 243-46.[8] Finally, the parties agreed at oral argument that the approach of the SFBC, supra and Merck, supra courts provided a helpful analytical framework for this case, and both of those cases applied Rales to their respective red flag allegations.

2. The Gestault Theory

Before turning to the substance of Plaintiffs' allegations, I address the parties' dispute about whether the red flag allegations must be considered separately or together. Plaintiffs argue that the Court consider the alleged red flags "holistically,"

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[8] An example of extreme indifference would be where, for example, the Board received "repeated notices from the Department of Education identifying serious infractions at [the corporation's] schools and threatening to shut them down if action is not taken." Fagin, 2007 WL 2176482 at *11. In contrast, allegations in a civil complaint by an ex-employee would not demonstrate extreme indifference. If such allegations "gave rise to the type of extreme indifference and failure to act that Abbott says creates enough of a likelihood of board member liability to justify a finding of demand futility, any board of any company with multiple operating units would constantly face liability." Id. Accord Johnson, 401 N.J.Super. at 245-46 (holding that allegations of red flags consisting of civil litigation complaints and SEC filings were distinguishable from Abbott). The allegations here, as explained in more detail herein, are more akin to the latter.

Tr. 17:4-5[9], whereas J&J argues that the Court must view the red flags in a more isolated fashion. So, for example, J&J argues that the Court should consider the off-label marketing red flag allegations separately from the illegal kickback allegations.

Plaintiffs cite In re American Intern. Group, Inc., 965 A.2d 763 (Del. Ch. 2009) ("In re AIG"), for their argument that all red flags should be considered together. in that case, the court suggested that the defendants' "attempt to focus on each scheme individually instead of on . . . the Complaint as a whole" was inappropriate. Id. at 796. Plaintiffs' reliance on In re AIG, however, is misplaced because that court was not discussing the Rule 23.1 particularized pleading standard when it made the aforesaid statement. Id. at 795. Rather, In re AIG applied the more lenient Rule 12(b)(6) standard. See id. ("[A]t this stage, is the basic issue [sic]: whether, under the plaintiff-friendly Rule 12(b)(6) standard, the Complaint states a claim that [the director defendants] committed a non-exculpated breach of their fiduciary duties."); id. at 811.

Nonetheless, several courts have held that red flags must be considered "cumulatively" in ascertaining whether a majority of the Board members "could not have fairly considered a demand ...." In re Bidz.com, Inc., 773 F.Supp.2d 844, 861 (C.D. Cal. 2011) ("Bidz"). See also In re Cray Inc., 431 F.Supp.2d 1114, 1121 (W.D. Wash. 2006) ("The [demand-futility] inquiry requires courts to look to the totality of the circumstances in assessing whether a complaint creates a "reasonable doubt"

[9] At oral argument, I referred to Plaintiffs' argument as a type of "Gestault theory."

concerning the board's independence or disinterestedness ...."); Veeco, supra at 274; McCall, 239 F.3d at 817; In re Cendant Corp. Derivative Litig., 189 F.R.D. 117, 128 (D.N.J. 1999) (citing Harris, supra).

These cases cite Harris v. Carter, 582 A.2d 222, 229 (Del. Ch. 1990), for that proposition. Harris stated that, in determining whether a director is disinterested and independent,

> no single factor—such as receipt of directorial compensation; family or social relationships; approval of the transaction attacked; or other relationships with the corporation (e.g., attorney or banker)—may itself be dispositive in any particular case. Rather the question is whether the accumulation of all factors creates . . . reasonable doubt [that the directors are disinterested and independent].

Id. at 799.

While J&J argues that the accumulation approach ignores the realities of J&J's corporate structure, J&J has not provided any legal support for its argument that each category of wrongful conduct alleged by Plaintiffs must be considered in isolation. That said, a relatively recent Delaware case suggests that it is rare that the accumulation approach will be successful for a plaintiff:

> Successful derivative plaintiffs . . . must focus intensely upon individual director's conflicts of interest or particular transactions that are beyond the bounds of business judgment. The appropriate analysis focuses upon each particular action, or failure to act, challenged by a plaintiff. Accumulating hundreds of allegations that individually would never withstand challenge under the [demand-futility] test, . . . in the hopes that collectively they will survive, is a strategy that succeeds in only the most uncommon and egregious of cases.

In re INFOUSA, Inc. Shareholders Litigation, 953 A.2d 963, 984 (Del. Ch. 2007) ("INFOUSA"). Nor is it appropriate for a shareholder-plaintiff to "attempt to compensate for the weakness of each particular allegation through an appeal to [the allegations'] collective unwholesomeness." Id. at 972. Yet, despite these pronouncements, that court concludes that the plaintiffs' "myriad allegations," "scattered throughout the complaint" in that case, demonstrated that demand would have been futile. Id. at 984-85.

In light of the aforesaid case law, it is my view that it is proper to consider Plaintiffs' red flag allegations in the aggregate. Even so, in light of the various types of wrongful conduct alleged in this case, at times, I find it appropriate to discuss the allegations categorically. So, I will follow J&J's approach of analyzing all off-label marketing allegations together, for example, while separately analyzing the kickback allegations. In my final analysis, though, I will consider whether the sum of all the allegations sufficiently demonstrates a majority of the Board was not disinterested or independent.

3. Plaintiffs' Allegations regarding Director Liability

Having clarified that the Court should view Plaintiffs' allegations as a whole, I now turn to the substance of Plaintiffs' allegations against the directors. As of April 13, 2010, the date of the initial complaint, the following eleven individuals served as directors on the Board: Coleman, Cullen, Lindquist, Mullin, Satcher, Weldon, Mulcahy,

Johns, Perez, Poon, and Prince.[10] Each of the directors is an outside director with the exception of Weldon, who is also J&J's CEO and Chairman of the Board. Both inside and outside directors are entitled to the presumption that they are independent and disinterested. See Fagin, 432 F.3d at 283 ("The fact that a director is also an officer, without more, is insufficient to establish the director's interest or lack of independence."); Bidz, 773 F.Supp.2d at 856 n.6 ("Delaware law . . . entitles both inside[ ] and outside directors to the presumption that they act independently, while faithful to their fiduciary duties."). It is Plaintiffs' obligation to allege particularized facts suggesting that a majority of the directors, in fact, are neither independent nor disinterested.

The earliest allegation of a "red flag" during the tenure of the named director defendants in the complaint is July 2003.[11] Plaintiffs allege that all directors, served

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[10] I focus upon the Board members serving at the time Plaintiffs' suit was instituted, rather than the directors who were serving during the challenged conduct or red flags, because the pertinent question under demand-futility analysis is whether the current directors would have fairly considered Plaintiffs' demand. See Johnson, supra at 238-39; INFOUSA, 953 A.2d at 985. In any event, the Board members remained relatively stable throughout the timeframe of the complaint, from 2003 through 2010. Three directors joined the Board after 2003: Johns in 2005, Prince in 2006; and Perez in 2007. In addition, Director Langbo served on the Board from 2003 until "April 2010." Compl., ¶ 32. (For purposes of this motion, I treat Plaintiffs' allegation as stating that Langbo was a Board member at the time the suit was filed on April 10, 2010.) All other members remained static. Where relevant to a particular red flag allegation, I will specify if certain individuals were not Board members at that time of that allegation.

[11] The earliest FDA warning letter was issued in January 1999, Compl., ¶ 173, but Plaintiffs' earliest red flag listed in their chronology of red flags is July 2003. Id. at ¶ 280.

on the Board from 2003 through 2010, with the exception of Johns, who became a director in 2005, Prince who became a director in 2006, and Perez who became a director in 2007. Because the remaining eight directors comprise a majority of the Board, I need not limit my analysis to any given time frame.

The other reason that I need not limit my analysis to a particular time frame is because, for almost all the red flags, Plaintiffs do not distinguish among the various directors but suggest that all directors received equal information. The only exception is Plaintiffs' allegations relating to CEO and Chairman Weldon. However, to the extent Plaintiffs allege that Weldon had knowledge of particular red flags, those allegations are unhelpful to Plaintiffs because they do not suggest that a majority of the Board had that same knowledge. See Intel, supra at 174-75. For this reason, I also do not distinguish between particular directors in my analysis. Instead, as indicated supra, I systematically address the various types and categories of allegations and then consider them as a whole.

In considering Plaintiffs' allegations, I reiterate that my focus is on whether the Plaintiffs have alleged particularized red flag allegations from which I can infer that a majority of the Board faces a substantial risk of personal liability because the directors acted in bad faith in failing to properly oversee the company. As the following discussion illustrates, Plaintiffs have failed to meet this rigorous pleading mandate.

a. Omnicare and DePuy Allegations

Plaintiffs' strongest director liability arguments relate to the Omnicare and DePuy kickback allegations. Plaintiffs' kickback allegations center on the Board's

conduct in failing to remedy J&J subsidiaries' Janssen and HCS's agreements with Omnicare that involved sale-bolstering kickbacks, as well as kickbacks paid by DuPuy, a different J&J subsidiary, to surgeons. I address each set of agreements in turn.

(1) Omnicare

As noted, Plaintiffs allege that Janssen and HCS entered into an agreement with Omnicare, a nursing home pharmacist company, whereby J&J provided illicit kickbacks in connection with J&J's off-label marketing schemes. Compl., ¶¶ 254-55. As an initial matter, Plaintiffs allege that the directors "understood" that the kickbacks violated the Federal Anti-Kickback Statute and were illegal. Id. at ¶ 257. This allegation is conclusory and must be rejected.

Second, Plaintiffs allege that there were several red flags that made the Board aware of Janssen's and HCS's conduct. In September 2005, Plaintiffs allege, J&J received a subpoena from the U.S. Attorney's Office for the District of Massachusettes, and that several Janssen and HCS employees were subpoenaed to testify before a grand jury. Id. at ¶ 281. Plaintiffs do not allege that the Board received a copy of these subpoenas. Rather, Plaintiffs allege that one of the officers on the Board, Defendant Russell C. Deyo, J&J's Chief Compliance Officer "sat on the Public Policy Committee of the Board, providing a critical additional source of reporting and information to this committee and, through it, the entire Board." Id.

The Complaint further alleges that "[t]he Company's Public Policy Advisory Committee consists both of directors and senior executive officers of the Company, including the General Counsel and senior executives in charge of government and

regulatory affairs." Id. at ¶ 299. According to Plaintiffs, "[t]he Committee's purpose includes reviewing and advising the Board on governmental and regulatory affairs involving public health issues. The members of the Public Policy Advisory Committee were regularly apprised by the General Counsel and other senior executives of the Company of regulatory affairs and compliance matters affecting the Company [sic] regularly reported to the full Board concerning significant issues and concerns arising at the committee's meetings." Id. As for the directors that served on the Public Policy Advisory Committee during 2005 and 2006, the Complaint alleges only that Directors Lindquist and Mullin were serving on the committee at that time. See id. at ¶ 297e-f.

In short, Plaintiffs assert that the Board knew about the 2005 subpoenas because Officer Deyo and Directors Lindquist and Mulllin sat on the Public Policy Committee. Indeed, Plaintiffs argued at oral argument that the Court may infer Board knowledge simply from the fact that certain members sat on committees of the Board that presumably discussed the various instances of corporate misconduct detailed in the Complaint.

Contrary to Plaintiffs' assertion, New Jersey and Delaware-based courts do not infer Board knowledge from committee membership alone. While other courts have looked solely to committee membership, see e.g., McCall v. Scott, 239 F.3d 808, 820 (6th Cir. 2001); Abbott, 325 F.3d at 806, Plaintiffs have not pointed to any authority from courts in New Jersey or Delaware for that proposition. Indeed, New Jersey and Delaware-based courts require Plaintiffs to allege, with particularity, how often the committee and the Board met, who on the committee communicated the corporate

misconduct to the Board, and how the Board responded to the information provided to them. See e.g., Desimone, supra, at 940 (holding that membership on Audit Committee is an insufficient basis for concluding that Board knowingly failed to act); Johnson, 401 N.J.Super. at 244-45. Accord Bidz, 773 F.Supp.2d at 858 n.7 (citing case for the proposition that "general allegations of the Audit Committee's responsibilities [are] insufficient to support allegations that the Audit Committee members knew of the alleged wrongdoing ...."); Markewich ex rel. Medtronic, Inc. v. Collins, 622 F.Supp.2d 802, (D.Minn. 2009) ("[I]it is well settled that committee membership is an insufficient basis on which to infer knowledge."). As explained by the court in Citigroup, "[a]lthough the members of the [Audit and Risk Management ("ARM")] Committee were charged with reviewing and ensuring the accuracy of Citigroup's financial statements under the ARM Committee charter, director liability is not measured by the aspirational standard established by the internal documents detailing a company's oversight system." 964 A.2d at 135.

Delaware and New Jersey-based courts require Plaintiffs to allege that committee members knew of particular corporate misconduct, and that the committee members communicated that knowledge to the Board. See Desimone, 924 A.2d at 943 (describing Saito v. McCall, 2004 WL 3029876 (Del. Ch. 2004), overruled on other grounds by Lambrecht v. O'Neal, 3 A.3d 277 (Del. 2010), in which "the complaint pled specific facts that the company's Audit Committee knew of certain accounting risks and that the risks were specifically discussed with some board members").

In Saito, for example, the complaint included specific allegations regarding audit

committee meetings with the company's auditor, in which meetings corporate misconduct was discussed. 2004 WL 3029876 at *2. These allegations included specific dates for the meetings, a list of who was present at the meetings, and who communicated the corporate misconduct-related information to the board members at each meeting. The court was willing to infer from these specific allegations that the directors who sat on the audit committee told the remaining directors about the corporate misconduct.

While Plaintiffs' allegations specify which Board members sat on the Public Policy Committee, there are no allegations regarding meeting dates, who was actually present at the meetings, or what subjects were discussed. Without this sort of factual detail, the Court cannot infer that a majority of the Board knew about the substance of the 2005 subpoenas, or any other subpoenas or government investigations disclosed in the 10-Ks, for that matter. Accord Intel, supra, at 174, 177-78 (stating that a court may infer director knowledge from committee members only where there are allegations that the directors attended specific meetings where the misconduct was discussed, allegations about how often the committee met, and allegations about who attended the meetings).

Indeed, the New Jersey Appellate Division held in Johnson v. Glassman that allegations of committee membership must include more detail than what has been plead here. That court quoted the following language of a District of Colorado decision with approval:

> All the plaintiffs' Amended Complaint . . . ostensibly

> demonstrates is that Carrier had an audit committee and the four independent outside director defendants were members of this committee during the period where the accounting improprieties occurred. That is not enough. Plaintiffs produce no evidence of the role, "if any, the Board or its members played in the internal processes of collecting and disseminating financial information." They aver no facts showing "how often" and "how long [the Audit Committee] met, who advised the committee, and whether the committee discussed and approved any of the allegedly improper accounting practices." Which specific oversight duties did the independent outside directors neglect? What specific action did these directors fail to take? What "specific red-or even yellow-flags were waved at the outside directors"? While plaintiffs claim to have alleged specific facts addressing these questions the Court can find none.

401 N.J.Super. 222, 244-45 (App. Div. 2008) (quoting Kenney v. Koenig, 426 F.Supp.2d 1175, 1183 (D.Colo. 2006)). This language applies with equal force here.

Plaintiffs further point to J&J's 2006 Form 10-K as evidence of director knowledge about the 2005 subpoenas. This allegation, unlike Plaintiffs' committee membership allegation, provides a basis for the Court to infer that the Board was aware of the subpoenas. The 2006 10-K states that

> [i]n September 2005, Johnson & Johnson received a subpoena from the United States Attorney's Office, District of Massachusetts, seeking documents related to sales and marketing of eight drugs to Omnicare, Inc., a manager of pharmaceutical benefits for long-term care facilities. The Johnson & Johnson subsidiaries involved are in the process of responding to the subpoena.

Johnson & Johnson Form 10-K (Annual Report) for period ending December 31, 2006

("2006 10-K") at 62.[12] Plaintiffs allege that directors Coleman, Cullen, Johns, Langbo, Lindquist, Mullin, Prince, Satcher and Weldon signed this 10-K form.

That the 10-K informed the directors about the subpoena, however, does not end my analysis. It is important to note at the outset that the 10-K's statement does not suggest that the subpoena involved alleged kickbacks, nor does it suggest that J&J or its subsidiaries acknowledged wrongdoing. Accordingly, the 10-K's statement is distinguishable from those cases that infer Board knowledge from a 10-K that explicitly acknowledges corporate misconduct. See e.g., In re Veeco Instr., Inc. Sec. Litig., 434 F.Supp. 2d 267, 277 (S.D.N.Y. 2006) (relying on 10-K statement indicating that "a deficiency existed in the internal control over financial reporting," yet the Board took no action for more than a year following this admission).

Indeed, as to this red flag, the pertinent question is not whether the Board knew about the subpoena but whether the subpoena is a determination of wrongdoing. At least one court has suggested that subpoenas, and other forms of preliminary matters in an investigation of corporate misconduct, do not shed light on whether the corporation actually engaged in misconduct. See Intel, supra at 175 (concluding that preliminary findings of government investigation entitled to little weight). I find this reasoning persuasive because such red flags do not suggest that a board was aware of

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[12] This language is taken from the 10-K and is not reflected in the Complaint. The Court notes that Plaintiffs would be well advised to either include the pertinent 10-K language upon which they rely in their Complaint or, at least, provide a page number to the 10-K with copies for the Court's review. It is not the Court's obligation to wade through pages of documents to locate the language Plaintiffs seek to invoke.

corporate misconduct—they suggest only that the board was aware that the company was under investigation.

Furthermore, disclosure of the subpoenas does not suggest that the Board knew that a refusal to act would be a breach of their fiduciary duties as directors. See Intel, supra at 174 (holding that directors' signatures on 10-K forms that show directors were aware of pending investigations do not support the inference that "the Directors had constructive knowledge that an alleged failure to respond to the 'red flags' would be a breach of their fiduciary duties, which is required under Delaware law."). As aptly stated by the court in Markewich, "Director Defendants cannot face a substantial likelihood of personal liability for unknown conduct that may be discovered." 622 F.Supp.2d at 810 (emphasis in original). This is not to say that the directors' knowledge of the subpoena may not be taken into consideration along with Plaintiffs' other red flag allegations, but it is insufficient on its own to demonstrate that the directors were not independent and disinterested. Cf. McCall, 239 F.3d at 821 ("[T]he lawsuit did not necessarily warn that improper practices were being employed systematically, [however,] the lawsuit . . . should be considered with all of the facts.")

Finally, the 2006 10-K indicated that the company was cooperating with the DOJ's investigation. In light of this language, the Court cannot conclude that disclosure of the subpoenas indicated that, even if there was corporate misconduct, that it was continuing. To the contrary, this language suggests that the corporation was responding appropriately and the directors did not need to respond at that point in time.

Plaintiffs next allege that the 2009 settlement agreement between Omnicare and the Department of Justice, regarding kickbacks Omnicare received from J&J between January 1999 and December 2004, constitutes a red flag that suggests the Board knew of the Omnicare kickback scheme. Id. at ¶ 270. I disagree. For one, the Omnicare settlement agreement was between Omnicare and the DOJ — not the J&J subsidiaries of Janssen and HCS and the DOJ. This distinction is important because Omnicare is not a J&J subsidiary. Therefore, whatever admissions of liability that Omnicare made in its settlement with the DOJ cannot be imputed to J&J or the J&J subsidiaries.[13]

In this connection, there is nothing in Plaintiffs' allegations to suggest that, within the settlement agreement, J&J or its subsidiaries admitted that the subsidiaries engaged in unlawful conduct. One of the key cases relied upon by Plaintiffs, Pfizer, supra, involved a settlement agreement in which the company admitted that it participated in an illegal marketing scheme. 722 F.Supp.2d at 457. Moreover, the company in that case admitted that it continued engaging in that sort of illegal behavior for several years after entering into a corporate compliance agreement with the Food and Drug Administration. Id. Needless to say, Plaintiffs' allegations do not point to any similar admission of longstanding wrongful conduct

[13] The parties have provided the Court with a copy of this settlement agreement.

after governmental intervention.[14]

Second, even if the Omnicare settlement suggests that Janssen and HCS engaged in wrongdoing, the settlement agreement was entered into in November 2, 2009, only five months before the initial complaint in this suit was filed in April of 2010. Courts that have held that a Board failed to act in bad faith, and therefore that the directors faced a substantial likelihood of personal liability, have relied on much longer periods of time of alleged Board inaction. See e.g., SFBC, 495 F.Supp.2d at 480 (three years); Abbott, 325 F.3d at 806-08 (six years); Veeco, 434 F.Supp. 2d 267, 277 (Board refused to act for over one year after corporation expressly admitted to lacking sufficient internal controls). In my view, five months does not provide a sufficient basis for inferring that the directors engaged in the sort egregious, conscious disregard of their duties like that alleged in those cases.

Another alleged red flag involves two qui tam suits filed against J&J (not the subsidiaries). Compl. at ¶ 271. According to the Complaint, two civil qui tam cases were filed in April 2009 and disclosed in the 2009 10-K. Id. at ¶ 282. The filing of these two complaints, alone, is not probative because knowledge of unsubstantiated qui tam allegations, on their own, do not suggest that the Board was aware of continued

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[14] That Plaintiffs allege criminal conduct, as opposed to only civil misconduct, is striking. Indeed, courts have found directors faced a substantial risk of liability where they failed to address "pervasive, diverse, and substantial . . . fraud at the highest levels" of a corporation. See AIG, 965 A.2d at 776. Here, even assuming that Janssen and HCS engaged in longstanding criminal misconduct, Plaintiffs' allegations here do not provide sufficient basis for this Court to conclude that the named director defendants consciously disregarded their role and acted in bad faith in not addressing Janssen's and HCS's conduct.

corporate misconduct.

That said, it is significant that the federal government intervened in the qui tam complaints in January 2010. Once the government intervenes in a qui tam suit, the allegations are transformed from that of a civil plaintiff to that of the government. See U.S. ex rel. Merena v. SmithKline Beecham Corp., 205 F.3d 97, 102 (3d Cir. 2000) (describing the process of government intervention as "tak[ing] over" claims originally asserted by the qui tam plaintiff) (discussing 31 U.S.C. § 3730). Noticeably absent from Plaintiff's allegations, however, are any facts indicating that the Board received copies of the qui tam complaints. To the extent the existence of the suits is reported in a 10-K form, that does not communicate to the directors anything about the nature of the claims asserted.[15] Without that information, the Court cannot discern whether the Board knew that Janssen and HCS continued to engage in kickback behavior after the 2005 subpoenas were issued.

More to the point, even assuming that the directors received additional information about the qui tam suits, those suits were not taken over by the government until January 2010. As noted, Plaintiffs' suit was filed only three months after that date. Hence this Court cannot infer, from that three-month time frame, that

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[15] Plaintiffs assert in their complaint that the qui tam complaints alleged that "the Company engaged in a 5-year scheme to illegally cause Omnicare to promote Risperdal and Levaquin." Compl., ¶ 271. However, the complaint does not allege that the directors were advised of these allegations. Nor does the 10-K include details about the qui tam complaints. This is likewise true of the additional details set forth in paragraph 272 of the Complaint; Plaintiffs do not allege that the directors received notice of these specific complaint allegations in any particular meeting, a 10-K, or through any other means.

the directors consciously chose, in bad faith, not to act. In other words, from that three months' time frame, the Court cannot conclude that a majority of the directors intended not to take any action.

Viewing all the Omnicare-related allegations as a whole, the Court does not find that there are particularized allegations of systematic illegal conduct that were ignored by the Board. This is not to say that Plaintiffs allegations are not disconcerting to the Court; Plaintiffs have not plead, at this juncture, sufficient facts from which the Court can infer that the directors acted in bad faith and, thereby, subjected themselves to personal liability. Accordingly, the Court cannot conclude that the Board faces a substantial likelihood of liability for Janssen's and HDC's conduct.

(1) DuPuy

With respect to DuPuy, the Complaint alleges that the company received a subpoena from the U.S. Attorney's Office in March 2005, and that a criminal complaint was filed against DuPuy in September of 2007, which complaint alleged that J&J engaged in illicit kickbacks from January 2002 through December 2006. Id. at ¶ 273. J&J, thereafter, entered into a settlement with the DOJ, hereinfater referred to as the "2007 Settlement". In addition, Plaintiffs allege that one of the officer defendants, Defendant Valeriani, knew of/or facilitated the illicit conduct. Id. at ¶ 276. Plaintiffs, further, allege that each of these red flags was disclosed in the 2007 10-K.

Plaintiffs' allegations are bereft of the detail necessary to satisfy Rule 23.1's heightened pleading standard. Upon review of the various 10-Ks cited by Plaintiffs in their Complaint, the 10-Ks do indicate the Board had some degree of knowledge of

DePuy's conduct. For example, the 2007 10-K states the following with respect to the 2005 subpoena and its aftermath:

> In March 2005, DePuy Orthopaedics, Inc. (DePuy), a Johnson & Johnson subsidiary, received a subpoena from the U.S. Attorney's Office, District of New Jersey, seeking records concerning contractual relationships between DePuy Orthopaedics and surgeons or surgeons-in-training involved in hip and knee replacement and reconstructive surgery. Other leading orthopaedic companies are known to have received a similar subpoena. DePuy Orthopaedics is responding to the subpoena as well as a follow-on subpoena for documents. A number of employees of DePuy have been subpoenaed to testify before a grand jury in connection with this investigation.

Johnson & Johnson Form 10-K (Annual Report) for period ending December 31, 2006 ("2007 10-K") at 73. The 10-K also acknowledges the 2006 U.S. Department of Justice subpoena and that five civil antitrust class actions were filed against DePuy. Id. According to the 10-K, DePuy cooperated with the investigation. See id.

In addition, the 2008 10-K contains details about the 2007 settlement. The 2008 10-K states:

> Th[e DuPuy] investigation was resolved by DePuy and the four other leading suppliers of hip and knee implants in late September 2007 by agreements with the U.S. Attorney's Office for the District of New Jersey. The settlements include an 18-month Deferred Prosecution Agreement (DPA), acceptance by each company of a monitor to assure compliance with the DPA and, with respect to four of the five companies, payment of settlement monies and entry into five year Corporate Integrity Agreements. DePuy paid $85 million as its settlement.

2008 10-K at 70.[16]

While Plaintiffs' allegations about DePuy's conduct and the 2007 settlement are troubling, just as with Plaintiff's Omnicare-related allegations, the allegations do not sufficiently demonstrate that the directors knew that DePuy systematically and continuously engaged in illicit conduct. It is true that the 2008 10-K disclosed the 2007 settlement, and it is significant that the settlement involved a Corporate Integrity Agreement ("CIA") and a Deferred Prosecution Agreement ("DPA"). Both the CIA and DPA suggest that DePuy engaged in some type of criminal misconduct. Indeed, Plaintiffs allege that DePuy was charged with a violation of the Anti-Kickback Statute. Compl., ¶ 277.

As an initial matter, and as noted above, it is not the Court's role to comb through the contents of the 10-Ks—Plaintiffs ought to place the salient portions of the 10-Ks in their Complaint if they wish to incorporate the substance thereof into their allegations. But even taking into account the above-quoted 10-K language, the Court finds no basis for inferring from the directors' signature on the various 10-Ks that they were aware of the extent of DePuy's misconduct and that the directors failed, in bad faith, to act in response to that misconduct.

For one, Defendant provided the Court with a copy of the DePuy settlement

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[16] Because this language is found in the 2008 10-K, reading the Complaint in the light most favorable to the Plaintiffs, the Court reads Plaintiffs' reference to the 2007 10-K as a typographical error. It makes sense that the 2007 DePuy settlement would not be disclosed in the 2007 10-K because each 10-K discusses the prior year's development. Thus, the 2007 10-K discusses development during the 2006 business year, while the 2008 10-K discusses 2007 developments.

agreement. The agreement clearly states that "DePuy denies that it engaged in any wrongdoing and specifically denies that any of the payments, services, or renumeration were illegal, improper, or resulted in any false or fraudulent claims." Robinson Cert., Exh. 1 at 2. The agreement further states that it is "neither an admission of any facts or liability by DePuy nor a concession by the United States that its claims are not well founded." Id. Therefore, it is not clear whether the settlement itself suggested to the Board that DePuy had engaged in illegal behavior.

Of course, one could argue that the Board should have known from the large amount of the settlement—$85 million— that DePuy must have engaged in illicit conduct. But, on the other hand, the Board may have reasonably concluded that the settlement reflected nothing more than a business decision on DePuy's part. Cf. Markowitz, supra at 812 (reasoning that civil settlements are often merely business decisions and not admissions of liability).[17] Even if the directors assumed that the settlement was merely a business decision, and that the directors' assumption was erroneous, nonetheless they would not be subject to liability if they made that assumption in good faith.

Moreover, the 10-K language does not specify the content of the CIA.[18] If the CIA placed an obligation on the Board to oversee DePuy's activities, that might suggest

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[17] While Markowitz spoke of civil cases, the same reasoning applies to this settlement which involved allegations of both civil and criminal misconduct. I find Markowitz's reasoning applicable here in light of the clear settlement agreement language indicating that DePuy did not acknowledge guilt.

[18] A copy of CIA was not submitted to the Court.

that individual directors could face a substantial likelihood of personal liability for failing to act in accordance with their contractual obligation. See Pfizer, supra, at 458. Neither the 2008 10-K nor Plaintiffs' allegations explain the terms of the CIA, nor do either clarify whether that agreement applied to management, officers, or directors. Moreover, Plaintiffs' allegations do not specify whether DePuy complied with the terms of the CIA or disregarded them.

With respect to the DPA, Plaintiffs allege that DePuy was charged with a violation of the Anti-Kickback Statute. As with the CIA, the 10-K merely states that a DPA exists; it does not explain the substance or terms of the DPA.[19] Therefore, the Court cannot infer from Plaintiffs' allegations that the Board knew that the DPA related to an Anti-Kickback Statute violation.

Moreover, the 2008 10-K states that the DPA was for only an eighteen month period. Plaintiffs' allegations do not specify what occurred after the expiration of the eighteen-month time period. If DePuy was not prosecuted at the end of that time frame, the DOJ's decision not to prosecute might suggest that DePuy altered its behavior to reflect the DOJ's objectives. Indeed, language in the 2010 10-K suggests this is the case: "[t]he term of the Monitor-ship under the Deferred Prosecution Agreement concluded on March 27, 2009, and an order dismissing all charges was entered on March 30, 2009." Johnson & Johnson Form 10-K (Annual Report) for period ending January 3, 2010 ("2010 10-K") at 61. If, on the other hand, the DOJ had

[19] No copy of the DPA was submitted to the Court.

threatened to extend the DPA's window or instituted a formal prosecution of DePuy, such actions would suggest that DePuy engaged in systematic conduct that the Board refused to address. This is the type of detail required by Rule 23.1, and the Complaint's allegations and references to the relevant 10-Ks are insufficient in this regard.

Plaintiffs' remaining DePuy allegations are likewise insufficient. Plaintiffs allege that the Attorney General of Massachusetts ("Massachusetts AG") issued a civil investigative demand regarding financial relationships between Massachusetts-based orthopedic surgeons and providers. The 2008 10-K states, however, that DePuy was cooperating with that investigation. 2008 10-K at 70. Moreover, it is not clear from Plaintiffs' allegations, or the 2008 10-K, to what conduct that investigation relates. If the investigation related solely to the same conduct that served as the basis for the DOJ's investigation, i.e., conduct that took place prior to the 2005 DOJ subpoena issuance, then the Massachusetts AG investigation does not provide a basis for inferring that DePuy continued to engage in the kick-back misconduct after 2005. In such an instance, the investigation would not provide a basis for inferring that the directors knew DePuy was engaging in kick-back misconduct over an extensive period of time.

If, in contrast, the Massachusetts AG investigation was about additional, post-2005 conduct, and Plaintiffs alleged that the directors knew the substance of those investigations, one could infer that the directors acted in bad faith in not taking action. Here, neither Plaintiffs' allegations in the Complaint nor the 2008 10-K recite facts

from which the Court could infer that DePuy engaged in the kick-back misconduct after 2005. Moreover, the 2008 10-K does not specify any detail about the substance of the investigation. Furthermore, even assuming that the conduct being probed by the Massachusettes AG was illegal, and that the Board had a duty to act in response to that conduct, with Plaintiffs having filed their complaint less than one year after the investigation began, the Court cannot conclude that the Board acted egregiously in not taking any action. Thus, the 10-K cannot serve as a basis for inferring what the Board knew about the Massachusetts AG's investigation or DePuy's post-2005 misconduct[20]

Similarly, as to Plaintiffs' allegation that the United States Senate Special Committee on Aging ("Aging Committee") commenced an investigation of DePuy's practices in 2008, that allegation does not specify the purpose of the investigation or its resolution. While the 2008 10-K notes that DePuy was cooperating with an investigation by the Aging Committee "as a follow-up to earlier inquiries" concerning the deferred prosecution agreement, id., it is not clear from Plaintiffs' allegations what aspects the Aging Committee was investigating or whether it was satisfied with DePuy's responses to its inquiries.

Plaintiffs, additionally, allege that the 2009 10-K disclosed that "DePuy receives

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[20] In this regard, the Court notes that the 2010 10-K states that the Massachusetts AG's investigation was civil, as opposed to criminal, in nature. See 2010 10-K at 61 (" In November 2007, the Attorney General of the Commonwealth of Massachusetts issued a Civil Investigative Demand to DePuy seeking information regarding financial relationships between a number of Massachusetts-based orthopedic surgeons and providers and DePuy. DePuy is responding to Massachusetts' additional requests.").

a subpoena from New Jersey AG regarding the financial interest of clinical investigators who performed clinical studies for DePuy." Compl., ¶ 282. As with Plaintiffs' other subpoena allegations, this assertion does not provide the detail the Court requires to ascertain its effect on the Board's knowledge.

Lastly, Plaintiffs allege that "J&J received a warning letter from the FDA relating to improper marketing of DePuy's TruMatch Personalized Solutions System and the Corail Hip System without the required marketing clearance or approval." Id. at ¶ 283. Plaintiffs do not allege that the Board received a copy of that warning letter. As to Weldon only, Plaintiffs allege in conclusory fashion that "as a member of the Executive Committee and as CEO and Chairman of the Executive Committee, [he] had knowledge of, and responsibility for, and approved and ultimately as CEO directed the use of the Company's . . . kickback strategy employed with DePuy ...." Id. at ¶ 311. But that Weldon received a copy of the warning letters does not speak to whether a majority of the Board was aware of them. Without allegations that Weldon shared his knowledge with the Board, the Court cannot conclude that the Board was ever aware of the FDA letters. Compare Pfizer, 722 F.Supp.2d at 460 (stating that "a large number of reports [were] made to members of the board [including] a large number of FDA violation notices and warning letters) (emphasis added).

Ultimately, viewing Plaintiffs' allegations as whole, Plaintiffs have not alleged a sustained, systemic failure of board oversight. To the extent Plaintiffs can amend their Complaint to provide more detail about the CIA and DPA, they may be able to meet the heightened pleading standard of Rule 23.1. To meet that standard, Plaintiffs

would have to allege, with particularized facts, that the Board had knowledge of the nature and pervasiveness of DePuy's corporate misconduct over an extended time frame, yet refused to act. The Court is skeptical that Plaintiffs could so plead in light of the statement in the 2010 10-K, for example, that "[t]he term of the Monitor-ship under the Deferred Prosecution Agreement concluded on March 27, 2009, and an order dismissing all charges was entered on March 30, 2009." 2010 10-K at 61. As noted, where it is clear that the misconduct was remedied within a short time frame, courts are not likely to conclude that Board members face personal liability for the misconduct. Thus, should Plaintiffs choose to amend, they would be remiss not to address the existence of all 10-K statements that suggest the corporate misconduct was remedied.

c. Product Recalls

As noted, Plaintiffs' product recall allegations relate to activities at several J&J subsidiaries—McNeil, Vision Care, and DePuy. Plaintiffs conceded at oral argument that the Vision Care and DePuy allegations occurred after the date of the initial complaint and should not factor into the Court's analysis. Hence I focus solely on the McNeil allegations.

That these allegations involve only one of J&J's 250 subsidiaries informs my analysis, and distinguishes this case from those that involve a corporation's primary or central operations. In SFBC, for example, that court was faced with allegations that related to the core operations of the drug trial company in that case—the unethical and unsafe manner by which it conducted drug trials. See 495 F.Supp.2d at 485. Here, in

contrast, Plaintiffs' allegations relate to the activities of only one out of many J&J subsidiaries. While the Board is obligated to oversee the entire J&J conglomerate, I view Plaintiffs' allegations with the expansive corporate structure of J&J in mind.

The types of red flags that Plaintiffs allege demonstrate the Board consciously failed to act in response to McNeil's legal violations mirror Plaintiffs' kickback allegations. For example, Plaintiffs allege that, "[]in 2004, the FDA sent a Warning Letter to J&J after a series of late 2003 inspections at various J&J manufacturing facilities found recurring '*systemic violations in the quality management system employed to ensure the safety and effectiveness of [J&J's] drug-eluting stents.*" (emphasis added). Compl., ¶ 86. That letter further noted that "J&J had failed to establish and maintain adequate procedures for corrective and preventive actions." Id. at ¶ 87. Noticeably, Plaintiffs do not allege that any of the FDA Warning Letters are reported in 10-K forms throughout the years addressed in the Complaint.

Nonetheless, based on J&J's alleged failures, the Complaint alleges, "the number of product recalls to which the Company was subjected grew significantly from 2004 to 2006, and continued throughout 2007." Id. at ¶ 88. The underlying quality and complaint problems were, according to the complaint, "well known to management." Id. at ¶ 91. Plaintiffs allege that "[a]n internal J&J report detailed manufacturing failures within [one of the manufacturing plants] that ultimately closed." Id. at ¶ 7.

According to the Complaint, in 2008, an "FDA report outlines an increasing number of complaints about consumer tablets of Tylenol Arthritis." Id. at ¶ 92. Also

in 2008, J&J allegedly engaged in a "phantom recall" of Motrin. Plaintiffs allege that, conducting the phantom recall, "J&J clearly knew what it was doing and why," id. at ¶ 100 (quoting Chairman Towns from House Committee meeting), and points to statements from members of J&J management regarding the illicit nature of the recall. See id. at ¶¶ 100-03. Plaintiffs allege that the phantom recall was conducted "[u]nder the Defendants' supervision." Id. at ¶ 9. An additional recall of Tylenol took place in 2009. Id. at ¶¶ 103-04.

The FDA inspected J&J's Las Piedras Facility in early 2010, at which facility medicines were manufactured and bottled. On January 10, 2010, "the FDA issued a scathing warning letter (the "Las Piedras Warning Letter") to Chairman and CEO Weldon," stating that "J&J did not take appropriate actions to resolve these issues. *Corporate management* has the responsibility to ensure the quality, safety, and integrity of its products. Neither upper management at J&J nor at McNeil Consumer Healthcare assured timely investigation and resolution of the issues." Id. at 109 (emphasis added). Representatives from the FDA subsequently met with J&J's senior management to address the company's pattern of misconduct. Id. at ¶ 110. Additional inspections took place later that year. Id. at ¶ 112.

According to Plaintiffs, "[d]espite the FDA's repeated efforts, J&J took no effective action to correct these endemic and dangerous patterns of operation which were known to the highest levels of J&J management." Id. In addition, Plaintiffs allege, "Defendants were apprised of the pertinent drug recalls, FDA warning letters, and increased facility reviews yet took no effective good faith actions to correct them."

Id. at ¶ 11. Plaintiffs make similar allegations with respect to the Fort Washington facility. See id. at ¶¶ 113-121.

Plaintiffs allege that, from 2008 to 2010, J&J failed to properly investigate the "alarming problems" with J&J"s children's medicines. "Beginning in April of 2010, J&J recalled various children and infants' medications. "These problems were reported to the Board, and the Company's Chairman and Chief Executive Officer ("CEO") has admitted, "[i]n 2008, there were adverse events reported that we knew." Id. at ¶ 12. Plaintiffs allege that the recalls were "the inevitable result of Defendants wilfull disregard for compliance and cGMP in the management of J&J's core business." Id. at ¶ 124.[21] Further, Plaintiffs allege, "J&J executive Colleen Goggins stated that the recall came down to 'people and leadership and process' [hence w]e've [since] made significant changes to leadership." Id.[22]

Furthermore, Plaintiffs allege, that "[o]n September 30, 2010, Chairman and CEO Weldon testified before the [House Committee] concerning the Company's numerous product recalls and conduct in response thereto. Among other things, Weldon conceded that the Phantom Recall was improper and a mistake." Id. at ¶ 162. Moreover, "Weldon admitted that the Company began to investigate the problem upon

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[21] cGMP are "current Good Manufacturing Practices." Id. at ¶ 9. The FDA enforces cGMP regulations. Id. at ¶ 57.

[22] Plaintiffs made additional allegations with regard to Acuvue contact lenses and other recalls. However, they conceded at oral argument that those allegations occurred after the initial complaint was filed and, therefore, may not be considered by the Court.

initial complaints, but decided to stop when complaints became less frequent." Id. at ¶ 163. In addition, other officers of J&J, and at least one also named as a defendant in this action, allegedly lied to Congress during the investigation. Id. at ¶ 161.

Taken together, the recall allegations do not suggest that the directors face substantial liability for their alleged inaction. As an initial matter, the Court notes that Plaintiffs often confuse officers with directors in their allegations. See e.g., id. at ¶ 161. (alleging that a J&J officer lied to Congress during the investigation). This is a grave error because, for purposes of demand-futility analysis, the question is whether a majority of the directors—not officers—could face liability for their conduct. In addition, Plaintiffs often refer to "J&J" when discussing the conduct of McNeil. While McNeil is a wholly-owned subsidiary of J&J, it is not accurate to refer to McNeil as J&J or vice versa. In holding true to the Complaint's allegations, I too refer to McNeil's conduct as "J&J's" conduct as encompassing that of its subsidiaries. However, my reference to J&J's action in this regard is not meant to indicate that I view the two separate entities as one and the same.

As noted, under Rales, Plaintiffs must allege that a majority of the directors would face a substantial likelihood of personal liability by complying with a shareholder's demand to pursue litigation, in order to show that the board could not have properly exercised independent and disinterested business judgment. Here, while Plaintiffs rely heavily on the issuance of FDA warning letters and the institution of litigation against J&J for its manufacturing problems, Plaintiffs have not alleged facts from which the Court could conclude that the Board had knowledge of the warning

letters and, in bad faith, failed to address systemic misconduct at McNeil.

Plaintiffs' strongest allegations of knowledge are that the manufacturing problems that ultimately led to the product recalls "were reported to the Board," and that Chairman/CEO Weldon stated in 2010 that "[i]n 2008, there were adverse events reported that we knew." Id. at ¶ 12. However, the statement that the problems "were reported to the Board" does not detail when, or to which directors, the problems were reported. Similarly, Weldon's alleged statement that "we knew" of the problems does not specify whether "we" refers to his colleagues on the board, officers of the corporation, or upper management generally. Nor does that statement name specific directors. To the extent this allegation implicates Weldon's own knowledge, it is insufficient to suggest that a majority of the board members had knowledge.[23]

Moreover, Plaintiffs' allegation that "J&J executive Colleen Goggins stated that the recall came down to 'people and leadership and process' [hence w]e've [since] made significant changes to leadership,"id. at ¶ 124, suggests that either the company or the Board made helpful changes in response to the product recall problem. Contrary to suggesting that directors would be held liable for a failure in oversight, this allegation arguably contradicts Plaintiffs' allegation that the Board failed to remedy the problem.

Finally, that there were comments in a Congressional House Committee meeting that disfavor J&J's practices has no bearing on whether the conduct was illegal, and

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[23] In this regard, Plaintiffs' allegations regarding the FDA Warning Letters also suggest that only Weldon received a copy of the letters. While he was copied on those letters, there are no specific allegations that he shared the letters with the Board.

the adequacy of the Board's response thereto, or lack thereof.[24] Moreover, Plaintiffs allege that Weldon testified before the Committee on September 30, 2010—six months after the Complaint was filed in this case. More to the point, his statements focus solely on the corporation's behavior rather than the Board's behavior. That he stated "the Company began to investigate the problem upon initial complaints, but decided to stop when complaints became less frequent." id. at ¶ 163, does not reveal anything about what the Board knew or did not know.

The same result obtains under a Caremark analysis. Under Caremark's three-part test, Plaintiffs must allege (1) that the directors knew or (2) should have known that violations of law were occurring and, in either event, (3) that directors took no steps in a good faith effort to prevent or remedy that situation. Because Plaintiffs fail to allege that each specific director knew or should have known that the manufacturing defects at the various plants, or the problems with the orthopedic devices, constituted actual violations of law, Plaintiffs fail to satisfy the Caremark formulation of the Rule 23.1 pleading standard as well.

Lastly, that Plaintiffs allege J&J made changes in leadership and engaged in voluntary recalls may suggest that J&J often responds "too little, too late" to a matter

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[24] In this connection, J&J further points to a September 28, 2010 letter from Representative Darrell Issa to the Department of Health and Human Services, in which Rep. Issa indicates that the FDA had been kept abreast of McNeil's efforts to effectuate the product recall. See Def. Open. Br. at 24 n.6. The Court need not consider this letter, however, in an effort to contradict the congressional hearing statement because the Court does not find the substance of the congressional hearing statement suggestive of Board knowledge.

one would expect to be of great corporate concern—patient safety. However, that J&J may have not responded appropriately, does not translate into a finding that the directors acted in bad faith and failed to properly discharge their duties. As noted, the exculpatory clause protects directors from merely negligent actions, and Plaintiffs' allegations simply do not suggest that a greater malfeasance, on the Board's part, occurred. In that connection, one consistent failure in Plaintiffs' Complaint is to allege how each specific red flag was resolved, or not resolved. Because of the Complaint's paucity of allegations on these specific sorts of issues, the Court cannot conclude that the individual directors faced a substantial likelihood of liability for a bad faith failure to oversee McNeil's recall-related activities.

d. Off-Label Marketing

Plaintiffs further allege that the J&J subsidiaries of Janssen, McNeil, and Scios engaged in an extensive off-label marketing campaign for three drugs — Risperdal, Topomax, and Natrecor — over the course of several years. The Complaint details a hodge-podge of internal J&J reports, news articles, and FDA warning letters issued to J&J, from 1999 onward, for both the Risperdal and Topomax medications. See Compl., ¶¶ 171-208.

(1) Risperdal

For Risperdal in particular, Plaintiffs allege that a confidential witness stated that Weldon directly participated in the decision to continue off-label marketing the product after FDA warning letters, directing J&J to curtail such practices, were issued. Id. at ¶ 180. J&J, through its subsidiary, continued off-label marketing for several

years after receiving multiple FDA warning letters and subpoenas from state attorney generals seeking information on J&J's marketing practices. Id. at ¶ 185-192.

Plaintiffs' Risperdal allegations fail to show that a majority of the directors are disinterested, or acted in bad faith. As with Plaintiffs' recall allegations, the FDA warning letters and subpoenas do not, alone, provide sufficient basis for this Court to infer director knowledge and acquiescence. In addition, existence of internal reports do not provide a sufficient basis for inferring knowledge and acquiescence unless Plaintiffs' allegations state, with particularity, that the reports were provided to the Board, and that the "directors acted with scienter, *i.e.*, that they had 'actual or constructive knowledge' that their conduct was legally improper." Intel, supra at 174 (quoting Wood v. Baum, 953 A.2d 136 (Del. 2008)). Furthermore, Plaintiffs have not alleged that the internal J&J reports were referenced in the 10-Ks. Thus, there is no basis for concluding that the Board members were aware of the reports and acted, in bad faith, in failing to respond properly. Again, as with Plaintiffs' other allegations, that Weldon may have known about the off-label marketing does not speak to whether a majority of the Board knew and consciously chose to disregard their duty of oversight.

Moreover, the Third Circuit reasoning in King, relating to those plaintiffs' claims or corporate marketing misconduct, apply here:

> The purported "red flags" that King cites all involve the company's marketing and sales practices. *King does not allege any specific connection between any of those practices and the board.* In the absence of facts showing that the board was aware of any of those actions, the [lower court's]

holding that King's complaint was inadequate was correct.

409 Fed.Appx. at 538 (emphasis added and internal citations omitted). Similarly, here, Plaintiffs' allegations fail to connect J&J's marketing practices with the Board. For these same reasons, Plaintiffs' claims likewise fail under a Caremark theory. Accord id.

(2) Topomax

For Topomax, Plaintiffs allege that J&J aggressively marketed off-label uses after the drug was respectively approved in 1996, 1999, and 2004 for three distinct, but specific, uses. Id. at ¶ 193. Clinical trials revealed severe side effects for off-label uses. Id. at ¶ 194. After several years of off-label marketing, qui tam suits were filed against J&J. Subsequently, in 2004, the FDA sent a warning letter to J&J, stating that the company's marketing practices were false and misleading. Id. at ¶ 203. In that letter, the FDA "demanded that J&J withdraw the false and misleading promotional materials from circulation and respond with a plan of action to disseminate complete Topamax risk information to the audiences exposed to the misleading materials." Id. at 204. In addition, "the Company received a multitude of subpoenas and requests for documents in connection with federal and state regulatory investigations of the off-label marketing of Topamax" in December of 2003 as well as in March of 2007. Id. at ¶ 206. According to the Complaint, Ortho pled guilty to criminal violations in April 2010. Id. at ¶ 207.

Plaintiffs allege that these occurrences resulted from a "complete breakdown of oversight that remained uncorrected during multiple years while the drug was

generating billions of dollars in revenues." Id. at ¶ 208. According to the complaint,

> [a]n informed board – aware of the limited nature of Topamax's approved indication – *should have been aware* that the only way for a drug like Topamax to achieve billions of dollars would be through extensive off-label promotion by the Company. As detailed below, the Board had knowledge throughout J&J's implementation of the off-label drug promotion schemes of the subpoenas, investigative demands and qui tam suits in connection with Topamax, as well as with other blockbuster drugs, Risperdal and Natrecor, much of which was specifically identified in Forms 10-K the Director Defendants personally executed.

Id. at ¶ 202 (emphasis added).

As is apparent from Plaintiffs' allegations, many of them speak only to the company's conduct as opposed to the Board's. As noted, this is simply insufficient under the case law. See King, 409 Fed.Appx. at 538. Also, Plaintiffs' reliance on the FDA Warning Letters and subpoenas is not helpful, for the reasons expressed above. In addition, that Ortho "pled guilty" to criminal violations in April 2010 is troubling. However, it is not clear from the Complaint what "pled guilty" means—whether Ortho entered into a settlement of the same nature as the McNeil settlement, where McNeil did not actually admit guilt, or whether Ortho appeared before a tribunal. As with Plaintiff's kickback allegations, Plaintiffs have also not alleged whether the Board knew about the settlement and plea. That fact is critical here where Plaintiffs allege that the guilty plea took place in April of 2010—the same month that Plaintiffs' Complaint was filed. Accordingly, I conclude that the Topomax allegations do not suggest that the Board could not have fairly considered a demand by Plaintiffs. For these same reasons, Plaintiffs' claim would fail under a Caremark theory.

(3) Natrecor

With respect to Natrecor, Plaintiffs allege that drug was initially developed by Scios, Inc. ("Scios"). Id. at ¶ 209. Scios was acquired by J&J in 2003 with board approval, "following comprehensive due diligence." Id. at ¶ 213. Plaintiffs allege that "[d]uring this due diligence, J&J learned about Scios's unlawful marketing scheme." Id. at ¶ 213. Confusingly, Plaintiffs further allege that J&J officers "learned during the due diligence process" that "J&J was directly involved in Scios's marketing of Natrecor for serial, outpatient use. J&J knew and approved of Scios's marketing goals and strategies that included marketing Natrecor for serial, outpatient use." Id. at ¶ 214 (emphasis added). It appears that, reading this allegation in context, that Plaintiffs mean to allege that J&J discovered Scios was continuing to engage in off-label marketing after Scios was acquired.

In addition, Plaintiffs allege that "even before the acquisition, J&J officers" learned during the due diligence process that:

(1) The FDA had only approved Natrecor for treatment of acute congestive heart failure, not treatment of chronic congestive heart failure;

(2) Despite Natrecor's approved use, Scios was marketing Natrecor for serial outpatient use;

(3) There would be significant upside potential if Scios were able to achieve an indication for chronic outpatient use – i.e., the sales forecast would increase by $330 million (from $600 million to $930 million);

(4) Scios's Business Plan included continuing to market Natrecor for outpatient use;

(5) Success in the outpatient setting would depend on Medicare continuing to reimburse for "treatment on a chronic basis," and that until Medicare's

view was clear, "it is a risk that is difficult to assess";

Id. at ¶ 214 (emphasis added).

Furthermore, Plaintiffs allege that a qui tam complaint alleges that Chairman/CEO Weldon approved and encouraged the off-label marketing of Natrecor, id. at ¶ 213, by visiting Scios and approving Scios' business plan "which set out the strategy to aggressively expand marketing Natrecor for outpatient use, and set separate sales goals for [off-label] sales." Id. at ¶ 215. Officer Defendant Scodari also allegedly approved the business plan. Id. at ¶ 216.

Plaintiffs further allege that, in response to growing concern in the medical community, J&J convened a Special Advisory Panel of outside cardiologists to "make recommendations concerning the use and further clinical studies of the drug ...." Id. at ¶ 231. The panel concluded that off-label uses should be limited. Id. at ¶ 231-32. Subsequently, federal Medicare and Medicaid refused to pay for off-label use of Natrecor. Id. at ¶ 238. And, a federal complaint alleging that J&J submitted false medicare claims withstood Rule 12(b)(6) dismissal in 2009. Id. at ¶ 239. "As the result of the decision of the Board and J&J's most senior executive officers to complete the Scios acquisition and to expand the off-label promotion of Natrecor for outpatient treatment," Plaintiffs allege, "the Company is potentially liable for hundreds of millions of dollars." Id. at ¶ 240.

While these allegations describe the fallout of the Scios purchase in a particularized fashion, they do not constitute particularized allegations of Board knowledge. Here, again, Plaintiffs' interchangeable use of "officers" with "the board"

is noticeable and inappropriate. While the Complaint alleges that the officers learned about Scios' practices through due diligence prior to and at the time of the acquisition, it does not allege that a majority of the Board learned that information through due diligence. The allegations, further, do not point to any specific director, other than Weldon, as having knowledge of Scios' practices.

As for Plaintiffs' due diligence allegations, the Court can infer only that Weldon and other officers had knowledge of what was acquired during the due diligence process. For the Court to infer that a majority of the directors knew the same information, Plaintiffs would have to plead particular meeting dates, subjects discussed, and attendees. Compare Saito, supra, at *2 (discussing complaint that included specific details of due diligence meetings).

In addition, because Plaintiffs allege that the Board had a functioning audit committee, and other oversight committees, that allegation undercuts Plaintiffs assertion that the Board failed to exercise oversight. Accord Johnson, 401 N.J.Super. at 245. As noted, to suggest that the audit committee was inadequate, Plaintiffs would have to allege how often the committees met, who advised them, and whether they discussed or approved any of the allegedly improper practices. See id. at 244-45. Conversely, to the extent Plaintiffs allege that the committee members knew of these practices, the same sort of detailed pleading is required. Finally, as noted above, existence of civil litigation also does not support an inference here, where no final resolution of that litigation had been reached. Although, the Complaint may have survived a Rule 12(b)(6) dismissal, the Complaint's allegations must be taken as true

at that stage. Accordingly, I do not find that Plaintiffs' Natrecor allegations demonstrate futility.

d. Biliary Stents

Plaintiffs biliary stent off-label marketing allegations are of the same kind as their Risperdal and Topomax allegations. See id. at ¶¶ 241-53. The red flags relating to the stents are a qui tam action, a Wall Street Journal article, and a government subpoena. For the reasons explained above, these red flags do not provide sufficient basis to infer Board knowledge.

4. Cumulative Effect

Taking all of Plaintiffs' red flag allegations as whole, the Court does not find a sufficient basis for inferring that a majority of the directors faced a substantial likelihood of personal liability in connection with what appears to be serious corporate misconduct on J&J's part.[25] As noted, none of the various types of red flags suggest that the Board acted in bad faith. Adding all of those allegations together does not lead me to a different conclusion in this case. While Plaintiffs' allegations are disconcerting, they do not contain the detail required by Rule 23.1 That said, if Plaintiffs amend their Complaint and add more particularized facts, they may be able to satisfy Rule 23.1's heightened pleading standard.

C. Nature of Dismissal

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[25] To the extent each particular allegation in Plaintiffs' 322-paragraph Complaint was not specifically addressed herein, the Court considered each allegation in reaching its decision.

Having concluded that Plaintiffs' allegations do not satisfy the heightened pleading standard of Rule 23.1, the Court must determine whether Plaintiffs' Complaint should be dismissed with or without prejudice. Some courts have dismissed demand-futility complaints with prejudice where Plaintiffs have not suggested that they could cure the defects in the "demand futility aspects" of their complaint. See e.g., Johnson v. Glassman, 401 N.J.Super. 222 (App. Div. 2008); Kanter v. Barella, Civ. No. 04-5542, 2005 WL 3088336 (D.N.J. Nov. 16, 2005) (dismissing demand futility claim with prejudice where plaintiff did not submit a proposed amended complaint) aff'd Kanter v. Barella, 489 F.3d 170, 181 (3d Cir. 2007). These courts find it significant that "[i]f plaintiffs were not already aware of the level of specificity by which they must plead their case in order to establish demand futility, [d]efendant's Motion to Dismiss certainly put them on notice [yet] [i]n responding, plaintiffs failed to provide any new factual allegations which might have cured their pleading deficiencies." Kenney v. Koenig, 426 F.Supp.2d 1175, 1188 (D.Colo. 2006).

A recent Delaware Supreme Court opinion, King v.VeriFone Holdings, Inc., 12 A.3d 1140 (Del. 2011), however, makes clear that this litigation-ending approach is disfavored by Delaware courts. In King, the Delaware Supreme Court reaffirmed that demand-futility complaints should be dismissed without prejudice and plaintiffs given the opportunity to pursue a books and record action, in state court, in order to buttress their insufficient allegations. Id. at 1146. A books and records action is an action, under state law, that grants shareholders the right to file suit in order to obtain access to inspect corporate records. See id. at 1145-46.

To be sure, numerous courts have explained that it is in the best interest of all parties and the court for plaintiffs to seek copies of corporate records prior to filing a demand-futility shareholder derivative action. See id. at 1145-48 (collecting cases). In this regard, King explains, "it is wasteful of the court's and the litigants' resources to have a regime that could require a corporation to litigate repeatedly the issue of demand futility." Id. at 1150-51. To ameliorate the additional burden that a post-complaint books and records action may place on a defendant-corporation, King advised that a court may dismiss the named plaintiff, deny lead plaintiff status to named plaintiff, or condition leave to amend on the plaintiff paying the defendant's attorneys' fees incurred in connection with the initial motion to dismiss. Id. at 1151-52. These sort of remedies sufficiently balance the interests of all parties, and the court, in streamlining litigation. Plaintiffs' approach here, of prematurely filing a demand futility action without having first sought corporate records, has the opposite effect.

Nonetheless, while shareholder-plaintiffs are well advised to obtain corporate records before filing a shareholder-derivative complaint, King holds that they may seek such records after filing suit in order to buttress their already-filed complaint—even after their shareholder-derivative complaint is dismissed. Id.[26] Other courts have

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[26] The court noted:

> By first prosecuting a Section 220 action to inspect books and records, the stockholder-plaintiff may be able to uncover particularized facts that would establish demand excusal in a subsequent derivative suit. A failure to proceed in that

followed this approach. For example, in In re Verifone, No. C 07–06347, 2009 WL 1458233 (N.D.Cal. May 26, 2009), a Northern District of California court dismissed a shareholder derivative complaint without prejudice, suggesting that the plaintiffs inspect the defendant-Delaware corporation's books and records pursuant to Section 220, and then file an amended consolidated complaint. See id. at *13.

I am persuaded that, while Plaintiffs' Complaint does not satisfy Rule 23.1's heightened pleading standard, that dismissal without prejudice is appropriate in this case. As in Delaware, shareholders of New Jersey corporations may bring a books and records action, under N.J.S.A. 14:5-28, to obtain copies of board minutes and other corporate records. See Cain v. Merck & Co., Inc., 415 N.J.Super. 319, 331 (App. Div. 2010). Although the New Jersey statute is not coterminous with the Delaware statute, see id. at 841 n.5, the New Jersey Appellate Division has acknowledged that a shareholder may petition a New Jersey court and seek inspection of records related to a pending law suit. Id. at 332 n.5, 335. It is, ultimately, left to the state court's discretion to "prescribe any limitations or conditions with reference to the inspection, or award any other or further relief as the court may deem just and proper." N.J.S.A. 14A:5-28(4). Nevertheless, it is clear that N.J.S.A. 14:5-28 grants shareholders the opportunity to seek corporate records even if the context of assisting them in pending

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> specific sequence, however, although ill-advised, has not heretofore been regarded as fatal. In several instances a stockholder-plaintiff initiated a derivative suit without first prosecuting a Section 220 books and records action.

Id. at 1145-46.

litigation.

In noting the possibility of a books and records action, I nonetheless express no opinion about whether an action brought under N.J.S.A. 14:5-28 would be successful. However, in light of the possibility of a books and records action, and the additional possibility that Plaintiffs may have other bases for asserting particularized facts in an amended complaint, I find it in the interest of justice to permit amendment. See Monaco v. City of Camden, 366 Fed.Appx. 330 (3d Cir. 2010) ("Leave to amend pleadings "shall be freely given when justice so requires." Fed.R.Civ.P. 15(a)."). And, granting Plaintiffs leave to amend may well not be futile if they take this opportunity to plead facts consistent with the dictates of this Opinion.

In deciding whether to institute a books and records action, and then to amend the Complaint, Plaintiffs should be advised that this Court, if faced with an amended complaint, is imbued with discretion to fashion a remedy that will ameliorate the additional burden imposed on J&J as a result of Plaintiffs' decision to have proceeded first in filing the Complaint without reviewing corporate records. As explained by the King Court, courts may impose remedies such as dismissing the named plaintiff from the suit, denying lead plaintiff status to the named plaintiff, or directing the plaintiffs to pay the defendant's attorneys fees. At this juncture, I express no opinion regarding whether any of these potential remedies, or that any remedy, is appropriate in this case.

For the foregoing reasons, the Court will dismiss Plaintiffs' Complaint without prejudice and grant Plaintiffs leave to amend. To be clear, the Court is in no way

suggesting that Plaintiffs will be able to allege facts necessary to satisfy the heightened pleading standard. Nevertheless, in the interest of justice, the Court finds it appropriate to grant Plaintiffs the opportunity to file an amended complaint with more particularized facts.

IV. CONCLUSION

For the reasons expressed above, Defendant's motion to dismiss is granted and Plaintiffs' Complaint is dismissed without prejudice with leave to amend. Plaintiffs shall inform the Court within thirty (30) days from the date of this Opinion whether they intend to amend the Complaint. If Plaintiffs choose to amend, the Court will determine an appropriate time frame for Plaintiffs to file their consolidated second amended complaint after conferring with all counsel.

Dated: September 29, 2011

/s/ Freda L. Wolfson
Hon. Freda L. Wolfson, U.S.D.J.